



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,749	03/03/2006	Lukas C. Amler	D0304 NP	9819
23914 7590 01/08/2008 LOUIS J. WILLE BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			EXAMINER GUSSOW, ANNE	
			ART UNIT 1643	PAPER NUMBER
			NOTIFICATION DATE 01/08/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@BMS.COM  
patents@bms.com  
eileen.immordino@bms.com

## Office Action Summary

Application No.

10/541,749

Applicant(s)

AMLER ET AL.

Examiner

Anne M. Gussow

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-4 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)                   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application         |
| Paper No(s)/Mail Date ____   | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignment</u> . |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a biomarker selected from the biomarkers in Table 4. In view of this Augustus (US PG PUB 2002/0102532, filed October 3, 2001) reads on the claim. Augustus teaches a method of treating cancer with agents targeting gene expression products. Augustus teaches one of these agents (SEQ ID No. 417) that is identical to 3-hydroxy-3-methylglutaryl-Coenzyme A synthase 2 (SEQ ID No. 1 in table 4) of the instant invention. Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked at to form a single general concept under rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups 1-139, claim(s) 1-4, drawn to a method for identifying a mammal that will respond therapeutically to a method of treating cancer by measuring the level of a biomarker selected from the listing in Tables 4 and 5. Each biomarker is a separate group.

2. The inventions listed as Groups 1-139 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: As set forth above, in view of the teachings of Augustus, the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one


or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow  
January 2, 2008



LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER

```
<!-- StartFragment -->RESULT 1
US-09-969-708-417
; Sequence 417, Application US/09969708
; Patent No. US20020102532A1
; GENERAL INFORMATION:
; APPLICANT: Augustus, Meena
; TITLE OF INVENTION: Cancer Gene Determination and Therapeutic Screening Using Signa
; TITLE OF INVENTION: Sets
; FILE REFERENCE: 689290-70
; CURRENT APPLICATION NUMBER: US/09/969,708
; CURRENT FILING DATE: 2001-10-03
; PRIOR APPLICATION NUMBER: US/60/237,606
; PRIOR FILING DATE: 2000-10-03
; PRIOR APPLICATION NUMBER: US/60/237,608
; PRIOR FILING DATE: 2000-10-03
; PRIOR APPLICATION NUMBER: US/60/237,425
; PRIOR FILING DATE: 2000-10-03
; NUMBER OF SEQ ID NOS: 658
; SOFTWARE: PatentIn version 3.0
; SEQ ID NO 417
; LENGTH: 2058
; TYPE: DNA
; ORGANISM: Homosapiens
US-09-969-708-417
```

```
Query Match          100.0%;  Score 2058;  DB 3;  Length 2058;
Best Local Similarity 100.0%;  Pred. No. 0;
Matches 2058;  Conservative 0;  Mismatches 0;  Indels 0;  Gaps 0;
```

```
Qy      1  CGGTTTCTGCTGGGTTTCTGAACTGCTGGGTTTCTGCTTGCTCCTCTGGAGATGCAGCGT  60
      |||
Db      1  CGGTTTCTGCTGGGTTTCTGAACTGCTGGGTTTCTGCTTGCTCCTCTGGAGATGCAGCGT  60

Qy     61  CTGTTGACTCCAGTGAAGCGCATTCTGCAACTGACAAGAGCGGTGCAGGAAACCTCCCTC  120
      |||
Db     61  CTGTTGACTCCAGTGAAGCGCATTCTGCAACTGACAAGAGCGGTGCAGGAAACCTCCCTC  120

Qy    121  ACACCTGCTCGCTGCTCCAGTAGCCACCAAAGGTTTCTACAGCCTCTGCTGTCCCC  180
      |||
Db    121  ACACCTGCTCGCTGCTCCAGTAGCCACCAAAGGTTTCTACAGCCTCTGCTGTCCCC  180

Qy    181  CTGGCCAAAACAGATACTTGGCCAAAGGACGTGGGCATCCTGGCCCTGGAGGTCTACTTC  240
      |||
Db    181  CTGGCCAAAACAGATACTTGGCCAAAGGACGTGGGCATCCTGGCCCTGGAGGTCTACTTC  240

Qy    241  CCAGCCCAATATGTGGACCAAAGTACCTGGAGAAGTATAACAATGTGGAAGCAGGAAAG  300
      |||
Db    241  CCAGCCCAATATGTGGACCAAAGTACCTGGAGAAGTATAACAATGTGGAAGCAGGAAAG  300

Qy    301  TATACAGTGGGCTTGGGCCAGACCCGTATGGGCTTCTGCTCAGTCCAAGAGGACATCAAC  360
      |||
Db    301  TATACAGTGGGCTTGGGCCAGACCCGTATGGGCTTCTGCTCAGTCCAAGAGGACATCAAC  360

Qy    361  TCCCTGTGCCTGACGGTGGTGCAACGGCTGATGGAGCGCATACAGCTCCCATGGGACTCT  420
      |||
Db    361  TCCCTGTGCCTGACGGTGGTGCAACGGCTGATGGAGCGCATACAGCTCCCATGGGACTCT  420

Qy    421  GTGGGCAGGCTGGAAGTAGGCACTGAGACCATCATTGACAAGTCCAAAGCTGTCAAAACA  480
      |||
Db    421  GTGGGCAGGCTGGAAGTAGGCACTGAGACCATCATTGACAAGTCCAAAGCTGTCAAAACA  480
```

Qy	481	GTGCTCATGGAACCTCTTCCAGGATTCAGGCAATACTGATATTGAGGGCATAGATACCACC	540
Db	481	GTGCTCATGGAACCTCTTCCAGGATTCAGGCAATACTGATATTGAGGGCATAGATACCACC	540
Qy	541	AATGCCTGCTACGGTGGTACTGCCTCCCTCTTCAATGCTGCCAACTGGATGGAGTCCAGT	600
Db	541	AATGCCTGCTACGGTGGTACTGCCTCCCTCTTCAATGCTGCCAACTGGATGGAGTCCAGT	600
Qy	601	TCCTGGGATGGTCGTTATGCCATGGTGGTCTGTGGAGACATTGCCGTCTATCCCAGTGGT	660
Db	601	TCCTGGGATGGTCGTTATGCCATGGTGGTCTGTGGAGACATTGCCGTCTATCCCAGTGGT	660
Qy	661	AATGCTCGTCCACAGGTGGGGCCGGAGCTGTGGCTATGCTGATTGGCCCAAAGGCCCT	720
Db	661	AATGCTCGTCCACAGGTGGGGCCGGAGCTGTGGCTATGCTGATTGGCCCAAAGGCCCT	720
Qy	721	CTGGCCCTGGAGCGAGGGCTGAGGGGAACCCATATGGAGAATGTGTATGACTTCTACAAA	780
Db	721	CTGGCCCTGGAGCGAGGGCTGAGGGGAACCCATATGGAGAATGTGTATGACTTCTACAAA	780
Qy	781	CCAAATTTGGCCTCGGAGTACCCAATAGTGGATGGGAAGCTTTCCATCCAGTGCTACTTG	840
Db	781	CCAAATTTGGCCTCGGAGTACCCAATAGTGGATGGGAAGCTTTCCATCCAGTGCTACTTG	840
Qy	841	CGGGCCTTGGATCGATGTTACACATCATACCGTAAAAAAATCCAGAATCAGTGGAAGCAA	900
Db	841	CGGGCCTTGGATCGATGTTACACATCATACCGTAAAAAAATCCAGAATCAGTGGAAGCAA	900
Qy	901	GCTGGCAGCGATCGACCCTTACCCTTGACGATTTACAGTATATGATCTTTCATACACCC	960
Db	901	GCTGGCAGCGATCGACCCTTACCCTTGACGATTTACAGTATATGATCTTTCATACACCC	960
Qy	961	TTTTGCAAGATGGTCCAGAAGTCTCTGGCTCGCCTGATGTTCAATGACTTCCTGTCAGCC	1020
Db	961	TTTTGCAAGATGGTCCAGAAGTCTCTGGCTCGCCTGATGTTCAATGACTTCCTGTCAGCC	1020
Qy	1021	AGCAGTGACACACAAACCAGCTTATATAAGGGGCTGGAGGCTTTGCGGGGGCTAAAGCTG	1080
Db	1021	AGCAGTGACACACAAACCAGCTTATATAAGGGGCTGGAGGCTTTGCGGGGGCTAAAGCTG	1080
Qy	1081	GAAGACACCTACACCAACAAGGACCTGGATAAAGCACTTCTAAAGGCCTCTCAGGACATG	1140
Db	1081	GAAGACACCTACACCAACAAGGACCTGGATAAAGCACTTCTAAAGGCCTCTCAGGACATG	1140
Qy	1141	TTGCACAAGAAAACCAAGGCTTCCCTTTACCTCTCCACTCACAATGGGAACATGTACACC	1200
Db	1141	TTGCACAAGAAAACCAAGGCTTCCCTTTACCTCTCCACTCACAATGGGAACATGTACACC	1200
Qy	1201	TCATCCCTGTACGGGTGCCTGGCCTCGCTTCTGTCCCACTCTGCCCCAAGAACTGGCT	1260
Db	1201	TCATCCCTGTACGGGTGCCTGGCCTCGCTTCTGTCCCACTCTGCCCCAAGAACTGGCT	1260
Qy	1261	GGCTCCAGGATTGGTGCCTTCTCTTATGGCTCTGGTTTAGCAGCAAGTTTCTTTTCATTT	1320
Db	1261	GGCTCCAGGATTGGTGCCTTCTCTTATGGCTCTGGTTTAGCAGCAAGTTTCTTTTCATTT	1320
Qy	1321	CGAGTATCCAGGATGCTGCTCCAGGCTCTCCCTTGGAACAAGTTGGTGTCCAGCACATCA	1380
Db	1321	CGAGTATCCAGGATGCTGCTCCAGGCTCTCCCTTGGAACAAGTTGGTGTCCAGCACATCA	1380
Qy	1381	GACCTGCCAAAACGCCTAGCCTCCGAAAGTGTGTGTCTCCTGAGGAGTTACAGAAATA	1440

```

      |||
Db      1381 GACCTGCCAAAACGCCTAGCCTCCCGAAAGTGTGTGTCTCCTGAGGAGTTCACAGAAATA 1440
      |||
Qy      1441 ATGAACCAAAGAGAGCAATTCTACCATAAGGTGAATTTCTCCCCACCTGGTGACACAAAC 1500
      |||
Db      1441 ATGAACCAAAGAGAGCAATTCTACCATAAGGTGAATTTCTCCCCACCTGGTGACACAAAC 1500
      |||
Qy      1501 AGCCTTTTCCCAGGTACTTGGTACCTGGAGCGAGTGGACGAGCAGCATCGCCGAAAGTAT 1560
      |||
Db      1501 AGCCTTTTCCCAGGTACTTGGTACCTGGAGCGAGTGGACGAGCAGCATCGCCGAAAGTAT 1560
      |||
Qy      1561 GCCCGGCGTCCCGTCTAAAGGTGTTCTGCAGATCCATGGAAAGCTTCCTGGGAAACGTAT 1620
      |||
Db      1561 GCCCGGCGTCCCGTCTAAAGGTGTTCTGCAGATCCATGGAAAGCTTCCTGGGAAACGTAT 1620
      |||
Qy      1621 GCTAGCAGAGCTTCTCCCCGTGAATCATATTTTAAAGATCCCACTCTTAGCTGGTAAATG 1680
      |||
Db      1621 GCTAGCAGAGCTTCTCCCCGTGAATCATATTTTAAAGATCCCACTCTTAGCTGGTAAATG 1680
      |||
Qy      1681 AATTTGAATCGACATAGTAGCCCCATAAGCATCAGCCCTGTAGAGTGAGGAGCCATCTCT 1740
      |||
Db      1681 AATTTGAATCGACATAGTAGCCCCATAAGCATCAGCCCTGTAGAGTGAGGAGCCATCTCT 1740
      |||
Qy      1741 AGCGGGCCCTTCATTCTCTCCATGCTGCAATCACTGTCTGGGCTTATGGTGCCTATGG 1800
      |||
Db      1741 AGCGGGCCCTTCATTCTCTCCATGCTGCAATCACTGTCTGGGCTTATGGTGCCTATGG 1800
      |||
Qy      1801 ACTAGGGGTCTTTGTGAAAGAGCAAGATGGAGCAATGGAGAGAAGACCTCTTCCTGAAT 1860
      |||
Db      1801 ACTAGGGGTCTTTGTGAAAGAGCAAGATGGAGCAATGGAGAGAAGACCTCTTCCTGAAT 1860
      |||
Qy      1861 CACTGGACTCCAGAAATGTGCATGCAGATCAGCTGTGCTTCAAGATCCAGATAAACTT 1920
      |||
Db      1861 CACTGGACTCCAGAAATGTGCATGCAGATCAGCTGTGCTTCAAGATCCAGATAAACTT 1920
      |||
Qy      1921 TCCTGTCATGTGTTAGAACCTTTATTATTATTAATATTGTTAACTTCTGTGCTGTTCTG 1980
      |||
Db      1921 TCCTGTCATGTGTTAGAACCTTTATTATTATTAATATTGTTAACTTCTGTGCTGTTCTG 1980
      |||
Qy      1981 TGAATCTCAAATTTTGTACCTTGTCTAAGCTAATATATAGCAATTAAAAAGAGAGAAA 2040
      |||
Db      1981 TGAATCTCAAATTTTGTACCTTGTCTAAGCTAATATATAGCAATTAAAAAGAGAGAAA 2040
      |||
Qy      2041 GAGAAAAAAAAAAAAAAAAA 2058
      |||
Db      2041 GAGAAAAAAAAAAAAAAAAA 2058
<!-- EndFragment -->

```